Senate Study Bill 1117 - Introduced

SEN	ATE FILE
ВУ	(PROPOSED COMMITTEE ON
	HEALTH AND HUMAN SERVICES
	BILL BY CHAIRPERSON EDLER)

A BILL FOR

- 1 An Act relating to the certificate of need process.
- 2 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

- 1 Section 1. Section 135.61, subsections 1, 14, 15, and 18,
- 2 Code 2023, are amended to read as follows:
- 3 1. "Affected persons" means, with respect to an application
- 4 for a certificate of need:
- 5 a. The person submitting the application.
- 6 b. Consumers who would be served by the new institutional
- 7 health service proposed in the application.
- 8 $\,$ $\,$ $\,$ $\,$ $\,$ $\,$ Each institutional health facility or health maintenance
- 9 organization which is located in the geographic area which
- 10 would appropriately be served by the new institutional
- 11 health service proposed in the application. The appropriate
- 12 geographic service area of each institutional health facility
- 13 or health maintenance organization shall be determined on a
- 14 uniform basis in accordance with criteria established in rules
- 15 adopted by the department.
- 16 d. Each institutional health facility or health maintenance
- 17 organization which, prior to receipt of the application by
- 18 the department, has formally indicated to the department
- 19 pursuant to this subchapter an intent to furnish in the future
- 20 institutional health services similar to the new institutional
- 21 health service proposed in the application.
- 22 e. Any other person designated as an affected person by
- 23 rules of the department.
- 24 f. Any payer or third-party payer for health services.
- 25 14. "Institutional health facility" means any of the
- 26 following, without regard to whether the facilities referred
- 27 to are publicly or privately owned or are organized for profit
- 28 or not or whether the facilities are part of or sponsored by a
- 29 health maintenance organization:
- 30 a. A hospital.
- 31 b. A health care facility.
- 32 c. An organized outpatient health facility.
- 33 d. An outpatient surgical facility.
- 34 e. A community mental health facility.
- 35 *f.* A birth center.

- l 15. "Institutional health service" means any health service
- 2 furnished in or through institutional health facilities or
- 3 health maintenance organizations, including mobile health
- 4 services.
- 5 18. "New institutional health service" or "changed
- 6 institutional health service" means any of the following:
- 7 a. The construction, development, or other establishment of
- 8 a new institutional health facility regardless of ownership.
- 9 b. Relocation of an institutional health facility.
- 10 c. Any capital expenditure, lease, or donation by or
- ll on behalf of an institutional health facility in excess
- 12 of one five million five hundred thousand dollars within a
- 13 twelve-month period.
- 14 d. A permanent change in the bed capacity, as determined
- 15 by the department, of an institutional health facility. For
- 16 purposes of this paragraph, a change is permanent if it is
- 17 intended to be effective for one year or more.
- 18 e. Any expenditure in excess of five hundred thousand
- 19 dollars by or on behalf of an institutional health facility for
- 20 health services which are or will be offered in or through an
- 21 institutional health facility at a specific time but which were
- 22 not offered on a regular basis in or through that institutional
- 23 health facility within the twelve-month period prior to that
- 24 time.
- 25 f. The deletion of one or more health services, previously
- 26 offered on a regular basis by an institutional health facility
- 27 or health maintenance organization or the relocation of one or
- 28 more health services from one physical facility to another.
- 29 g. Any acquisition by or on behalf of a health care provider
- 30 or a group of health care providers of any piece of replacement
- 31 equipment with a value in excess of one million five hundred
- 32 thousand dollars, whether acquired by purchase, lease, or
- 33 donation.
- 34 h. Any acquisition by or on behalf of a health care provider
- 35 or group of health care providers of any piece of equipment

- 1 with a value in excess of one million five hundred thousand
- 2 dollars, whether acquired by purchase, lease, or donation,
- 3 which results in the offering or development of a health
- 4 service not previously provided. A mobile service provided
- 5 on a contract basis is not considered to have been previously
- 6 provided by a health care provider or group of health care
- 7 providers.
- 8 i. Any acquisition by or on behalf of an institutional
- 9 health facility or a health maintenance organization of any
- 10 piece of replacement equipment with a value in excess of one
- 11 million five hundred thousand dollars, whether acquired by
- 12 purchase, lease, or donation.
- 13 j. Any acquisition by or on behalf of an institutional
- 14 health facility or health maintenance organization of any
- 15 piece of equipment with a value in excess of one million five
- 16 hundred thousand dollars, whether acquired by purchase, lease,
- 17 or donation, which results in the offering or development of
- 18 a health service not previously provided. A mobile service
- 19 provided on a contract basis is not considered to have been
- 20 previously provided by an institutional health facility.
- 21 k. Any air transportation service for transportation of
- 22 patients or medical personnel offered through an institutional
- 23 health facility at a specific time but which was not offered
- 24 on a regular basis in or through that institutional health
- 25 facility within the twelve-month period prior to the specific
- 26 time.
- 27 1. Any mobile health service with a value in excess of one
- 28 million five hundred thousand dollars.
- 29 m. Any of the following:
- 30 (1) Cardiac catheterization service.
- 31 (2) Open heart surgical service.
- 32 (3) Organ transplantation service.
- 33 (4) Radiation therapy service applying ionizing radiation
- 34 for the treatment of malignant disease using megavoltage
- 35 external beam equipment.

- 1 Sec. 2. Section 135.61, subsections 2 and 16, Code 2023, are
- 2 amended by striking the subsections.
- 3 Sec. 3. Section 135.62, subsection 2, paragraphs a, b, and
- 4 c, Code 2023, are amended to read as follows:
- 5 a. Qualifications. The members of the council shall be
- 6 chosen so that the council as a whole is broadly representative
- 7 of various geographical areas of the state and no more than
- 8 three of its members are affiliated with the same political
- 9 party. Each council member shall be a person who has
- 10 demonstrated by prior activities an informed concern for the
- 11 planning and delivery of health services. A member of the
- 12 council and any spouse of a member shall not, during the
- 13 time that member is serving on the council, do either of the
- 14 following:
- 15 (1) Be a health care provider nor be otherwise directly or
- 16 indirectly engaged in the delivery of health care services nor
- 17 have a material financial interest in the providing or delivery
- 18 of health services.
- 19 (2) Serve as a member of any board or other policymaking
- 20 or advisory body of an institutional health facility, a health
- 21 maintenance organization, or any health or hospital insurer.
- 22 b. Appointments. Terms of council members shall be six
- 23 three years, beginning and ending as provided in section
- 24 69.19. A member shall be appointed in each odd-numbered
- 25 year to succeed each member whose term expires in that year.
- 26 Vacancies shall be filled by the governor for the balance of
- 27 the unexpired term. Each appointment to the council is subject
- 28 to confirmation by the senate. A council member is ineligible
- 29 for appointment to a second consecutive term, unless first
- 30 appointed to an unexpired term of three years or less.
- 31 c. Chairperson. The governor council shall designate one
- 32 of the council members as chairperson. That designation may
- 33 be changed not later than July 1 of any odd-numbered year,
- 34 effective on the date of the organizational meeting held in
- 35 that year under paragraph "d".

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- 1 Sec. 4. Section 135.63, subsection 1, Code 2023, is amended 2 to read as follows:
- A new institutional health service or changed
- 4 institutional health service shall not be offered or developed
- 5 in this state without prior application to the department
- 6 for and receipt of a certificate of need, pursuant to
- 7 this subchapter. The application shall be made upon forms
- 8 furnished or prescribed by the department and shall contain
- 9 such information as the department may require under this
- 10 subchapter. The application shall be accompanied by an
- 11 economic impact statement that includes information specified
- 12 by rule to assist the department and the council in the
- 13 evaluation of the application pursuant to section 135.64.
- 14 The application shall be accompanied by a fee equivalent to
- 15 three-tenths of one percent of the anticipated cost of the
- 16 project with a minimum fee of six hundred dollars and a maximum
- 17 fee of twenty-one of one thousand dollars. The fee shall be
- 18 remitted by the department to the treasurer of state, who shall
- 19 place it in the general fund of the state. If an application
- 20 is voluntarily withdrawn within thirty calendar days after
- 21 submission, seventy-five percent of the application fee shall
- 22 be refunded; if the application is voluntarily withdrawn more
- 23 than thirty but within sixty days after submission, fifty
- 24 percent of the application fee shall be refunded; if the
- 25 application is withdrawn voluntarily more than sixty days
- 26 after submission, twenty-five percent of the application fee
- 27 shall be refunded. Notwithstanding the required payment of
- 28 an application fee under this subsection, an applicant for a
- 29 new institutional health service or a changed institutional
- 30 health service offered or developed by an intermediate care
- 31 facility for persons with an intellectual disability or an
- 32 intermediate care facility for persons with mental illness as
- 33 defined pursuant to section 135C.1 is exempt from payment of
- 34 the application fee.
- 35 Sec. 5. Section 135.63, subsection 2, paragraphs a and e,

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- 1 Code 2023, are amended to read as follows:
- a. Private offices and private clinics of an individual
- 3 physician, dentist, or other practitioner or group of
- 4 health care providers, except as provided by section 135.61,
- 5 subsection 18, paragraphs "g", "h", and "m", and section 135.61,
- 6 subsections 20 and 21.
- 7 e. A health maintenance organization or combination of
- 8 health maintenance organizations or an institutional health
- 9 facility controlled directly or indirectly by a health
- 10 maintenance organization or combination of health maintenance
- ll organizations, except when the health maintenance organization
- 12 or combination of health maintenance organizations does any of
- 13 the following:
- 14 (1) Constructs constructs, develops, renovates, relocates,
- 15 or otherwise establishes an institutional health facility.
- 16 (2) Acquires major medical equipment as provided by section
- 17 135.61, subsection 18, paragraphs "i" and "j".
- 18 Sec. 6. Section 135.63, subsection 2, paragraph h, Code
- 19 2023, is amended by striking the paragraph.
- Sec. 7. Section 135.63, subsection 4, unnumbered paragraph
- 21 1, Code 2023, is amended to read as follows:
- 22 A copy of the application shall be sent to the department
- 23 of human services at the time the application is submitted to
- 24 the Iowa department of public health. The department shall not
- 25 process applications for and the council shall not consider a
- 26 new or changed institutional health service for an intermediate
- 27 care facility for persons with an intellectual disability
- 28 unless both of the following conditions are met:
- Sec. 8. Section 135.66, subsections 1 and 2, Code 2023, are
- 30 amended to read as follows:
- 31 1. a. Within fifteen business days after receipt of an
- 32 application for a certificate of need, the department shall
- 33 examine the application for form and completeness and accept
- 34 or reject it. An application shall be rejected only if it
- 35 fails to provide all information required by the department

- 1 pursuant to section 135.63, subsection 1. The department shall
- 2 promptly return to the applicant any rejected application, with
- 3 an explanation of the reasons for its rejection.
- 4 b. Within thirty days after notifying the applicant of
- 5 rejection of the application, the applicant may resubmit a
- 6 revised application for review under this subsection and shall
- 7 not be subject to payment of another required application
- 8 fee pursuant to section 135.63. If a subsequent rejection
- 9 is issued, the applicant shall resubmit the application in
- 10 accordance with and shall be subject to the procedure and
- 11 requirements for an initial application.
- 12 2. Upon acceptance of an application for a certificate
- 13 of need, the department shall promptly undertake to notify
- 14 all affected persons in writing that formal review of the
- 15 application has been initiated. Notification to those affected
- 16 persons who are consumers or third-party payers or other
- 17 payers for health services may be provided by distribution of
- 18 the pertinent information to the news media by an electronic
- 19 distribution method available to the department.
- Sec. 9. Section 135.67, subsection 1, Code 2023, is amended
- 21 to read as follows:
- 22 1. The department may waive the letter of intent procedures
- 23 prescribed by section 135.65 and substitute conduct a summary
- 24 review procedure, which shall be established by rules of the
- 25 department, when it accepts an application for a certificate of
- 26 need for a project which meets any of the following criteria
- 27 in paragraphs "a" through "e":
- 28 a. A project which is limited to repair or replacement of a
- 29 facility or equipment damaged or destroyed by a disaster, and
- 30 which will not expand the facility nor increase the services
- 31 provided beyond the level existing prior to the disaster.
- 32 b. A project necessary to enable the facility or service to
- 33 achieve or maintain compliance with federal, state, or other
- 34 appropriate licensing, certification, or safety requirements.
- 35 c. A project which will not change the existing bed capacity

- 1 of the applicant's facility or service, as determined by the
- 2 department, by more than ten percent or ten beds, whichever is
- 3 less, over a two-year period.
- 4 d. A project the total cost of which will not exceed one
- 5 hundred fifty thousand dollars.
- 6 e. d. Any other project for which the applicant proposes
- 7 and the department agrees to summary review.
- 8 Sec. 10. Section 135.69, Code 2023, is amended to read as
- 9 follows:
- 10 135.69 Council to make final decision.
- 11 1. The department shall complete its formal review of
- 12 the application within $\frac{1}{ninety}$ thirty days after acceptance
- 13 of the application, except as otherwise provided by section
- 14 135.72, subsection 4. Upon completion of the formal review,
- 15 the council shall approve or deny the application. The council
- 16 shall issue written findings stating the basis for its decision
- 17 on the application, and the department shall send copies of
- 18 the council's decision and the written findings supporting
- 19 the decision to the applicant and to any other person who so
- 20 requests.
- 21 2. Failure by the council to issue a written decision on an
- 22 application for a certificate of need within the time required
- 23 by this section shall constitute denial approval of and final
- 24 administrative action on the application.
- Sec. 11. Section 135.72, subsection 4, Code 2023, is amended
- 26 to read as follows:
- 27 4. Criteria for determining when it is not feasible to
- 28 complete formal review of an application for a certificate of
- 29 need within the time limits specified in section 135.69. The
- 30 rules adopted under this subsection shall include criteria for
- 31 determining whether an application proposes introduction of
- 32 technologically innovative equipment, and if so, procedures
- 33 to be followed in reviewing the application. However, a rule
- 34 adopted under this subsection shall not permit a deferral of
- 35 more than sixty thirty days beyond the time when a decision is

- 1 required under section 135.69, unless both the applicant and
- 2 the department agree to a longer deferment.
- 3 Sec. 12. Section 135.73, subsection 1, Code 2023, is amended
- 4 to read as follows:
- Any party constructing a new institutional health
- 6 facility or an addition to or renovation of an existing
- 7 institutional health facility without first obtaining a
- 8 certificate of need or, in the case of a mobile health service,
- 9 ascertaining that the mobile health service has received
- 10 certificate of need approval, as required by this subchapter,
- 11 shall be denied licensure or change of licensure by the
- 12 appropriate responsible licensing agency of this state.
- 13 Sec. 13. Section 135.131, subsection 1, paragraph a, Code
- 14 2023, is amended to read as follows:
- 15 a. "Birth center" means birth center as defined in section
- 16 135.61 a facility or institution, which is not an ambulatory
- 17 surgical center or a hospital or in a hospital, in which
- 18 births are planned to occur following a normal, uncomplicated,
- 19 low-risk pregnancy.
- Sec. 14. Section 135P.1, Code 2023, is amended to read as
- 21 follows:
- 22 135P.1 Definitions.
- 23 For the purposes of this chapter, unless the context
- 24 otherwise requires:
- 25 1. "Adverse health care incident" means an objective and
- 26 definable outcome arising from or related to patient care that
- 27 results in the death or physical injury of a patient.
- 28 2. "Health care provider" means a physician or osteopathic
- 29 physician licensed under chapter 148, a physician assistant
- 30 licensed and practicing under a supervising physician pursuant
- 31 to chapter 148C, a podiatrist licensed under chapter 149, a
- 32 chiropractor licensed under chapter 151, a licensed practical
- 33 nurse, a registered nurse, or an advanced registered nurse
- 34 practitioner licensed under chapter 152 or 152E, a dentist
- 35 licensed under chapter 153, an optometrist licensed under

- 1 chapter 154, a pharmacist licensed under chapter 155A, or
- 2 any other person who is licensed, certified, or otherwise
- 3 authorized or permitted by the law of this state to administer
- 4 health care in the ordinary course of business or in the
- 5 practice of a profession.
- 6 3. "Health facility" means an institutional health facility
- 7 as defined in section 135.61, a hospice licensed under chapter
- 8 135J, a home health agency as defined in section 144D.1, an
- 9 assisted living program certified under chapter 231C, a clinic,
- 10 a community health center, or the university of Iowa hospitals
- 11 and clinics, and includes any corporation, professional
- 12 corporation, partnership, limited liability company, limited
- 13 liability partnership, or other entity comprised of such health
- 14 facilities.
- 15 4. "Institutional health facility" means any of the
- 16 following, without regard to whether the facilities referred
- 17 to are publicly or privately owned or are organized for profit
- 18 or not, or whether the facilities are part of or sponsored by a
- 19 health maintenance organization:
- 20 a. A hospital.
- 21 b. A health care facility.
- 22 c. An organized outpatient health facility.
- 23 d. An outpatient surgical facility.
- 24 e. A community mental health facility.
- 25 f. A birth center.
- 26 4. 5. "Open discussion" means all communications that are
- 27 made under section 135P.3, and includes all memoranda, work
- 28 products, documents, and other materials that are prepared
- 29 for or submitted in the course of or in connection with
- 30 communications under section 135P.3.
- 31 5. 6. "Patient" means a person who receives medical care
- 32 from a health care provider, or if the person is a minor,
- 33 deceased, or incapacitated, the person's legal representative.
- 34 Sec. 15. REPEAL. Section 135.65, Code 2023, is repealed.
- 35 EXPLANATION

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The inclusion of this explanation does not constitute agreement with the explanation's substance by the members of the general assembly.

- This bill relates to the health facilities council (HFC) and the certificate of need (CON) process.
- 5 The bill amends the definition of "affected person" with
- 6 respect to an application for CON to eliminate from inclusion
- 7 in the definition each institutional health facility or
- 8 health maintenance organization which, prior to receipt of
- 9 the application, has formally indicated an intent to furnish
- 10 in the future institutional health services similar to the
- 11 new institutional health service proposed in the application;
- 12 any other person designated as an affected person by rules of
- 13 the department; and any payer or third-party payer for health
- 14 services.
- 15 The bill amends the definition of "institutional health
- 16 facility" by removing a "community mental health facility"
- 17 and a "birth center" from inclusion in the definition,
- 18 thereby making these facilities and centers exempt from CON
- 19 requirements.
- 20 The bill amends the definition of "new institutional
- 21 health service" or "changed institutional health service"
- 22 by striking many of the services included in current Code
- 23 and only including: the construction, development, or other
- 24 establishment of a new institutional health facility regardless
- 25 of ownership; relocation of an institutional health facility;
- 26 any capital expenditure, lease, or donation by or on behalf of
- 27 an institutional health facility in excess of \$5 million within
- 28 a 12-month period, and a permanent change (effective for one
- 29 year or more) in the bed capacity of an institutional health
- 30 facility. Under the bill, only these services included in the
- 31 definition are subject to CON requirements.
- 32 The bill eliminates terms defined and references to these
- 33 terms under the Code chapter that are no longer necessary due
- 34 to provisions of the bill including the definitions of "birth
- 35 center" and "mobile health service".

- 1 The bill amends the qualifications for members of the HFC by
- 2 retaining the requirement that members of the council be chosen
- 3 so that the council as a whole is broadly representative of
- 4 various geographical areas of the state, but eliminating the
- 5 requirements that no more than three members are affiliated
- 6 with the same political party and that each council member be
- 7 a person who has demonstrated by prior activities an informed
- 8 concern for the planning and delivery of health services.
- 9 Code section 69.16 requires that all appointive bodies if
- 10 not otherwise provided by law shall be bipartisan in their
- 11 composition.
- 12 The bill amends HFC member appointment provisions to provide
- 13 that terms of council members shall be three rather than six
- 14 years, and by eliminating the requirements that a member shall
- 15 be appointed in each odd-numbered year to succeed each member
- 16 whose term expires in that year, that vacancies shall be filled
- 17 by the governor for the balance of the unexpired term, and that
- 18 each appointment to the council is subject to confirmation by
- 19 the senate. The bill also removes the provision that a council
- 20 member is ineligible for appointment to a second consecutive
- 21 term, unless first appointed to an unexpired term of three
- 22 years or less.
- 23 With regard to the chairperson of the HFC, the bill provides
- 24 that the council, rather than the governor, shall designate one
- 25 of the council members as chairperson.
- 26 The bill amends the fee requirements relating to the
- 27 application for a CON to provide that instead of a fee
- 28 equivalent to three-tenths of 1 percent of the anticipated
- 29 cost of the project with a minimum fee of \$600 and a maximum
- 30 fee of \$21,000, the fee is \$1,000. The bill retains the
- 31 provision that provides that if an application is voluntarily
- 32 withdrawn within 30 calendar days after submission, 75 percent
- 33 of the application fee shall be refunded, but eliminates
- 34 the proportionate refund of any portion of the fee if the
- 35 application is voluntarily withdrawn beyond that 30-day period.

- 1 The bill requires that an application be accompanied by an
- 2 economic impact statement that includes information required by
- 3 rule to assist in evaluation of the application.
- 4 Due to the combining of the department of human services
- 5 (DHS) and the department of public health (DPH) into the
- 6 department of health and human services (HHS), the bill
- 7 eliminates the requirement that a copy of the application for
- 8 CON be sent to DHS at the time the application is submitted to
- 9 DPH.
- 10 Current law provides that within 15 business days after
- 11 receipt of an application for a CON, HHS shall examine the
- 12 application and accept or reject it, and that HHS shall
- 13 promptly return to the applicant any rejected application, with
- 14 an explanation of the reasons for its rejection. The bill adds
- 15 a provision that within 30 days after notifying the applicant
- 16 of rejection of the application, the applicant may resubmit
- 17 a revised application for review and shall not be subject to
- 18 payment of another required application fee. Further, if a
- 19 subsequent rejection is issued, the applicant shall resubmit
- 20 the application in accordance with and shall be subject to the
- 21 procedure and requirements for an initial application.
- 22 Current law provides that upon acceptance of an application
- 23 for a CON, HHS shall promptly notify all affected persons
- 24 in writing that formal review of the application has been
- 25 initiated, and that notification to those affected persons who
- 26 are consumers or third-party payers or other payers for health
- 27 services may be provided notification by distribution of the
- 28 pertinent information to the news media. The bill amends this
- 29 provision to eliminate the reference to third-party payers or
- 30 other payers as they are no longer included in the definition
- 31 of affected persons, and provides that notification to affected
- 32 persons who are consumers may be provided by an electronic
- 33 distribution method available to HHS.
- 34 The bill eliminates the letter of intent procedure requiring
- 35 that before applying for a CON, the sponsor of a proposed

- 1 new institutional health service or changed institutional
- 2 health service submit to HHS a letter of intent to offer or
- 3 develop a service requiring a CON, as soon as possible after
- 4 initiation of the applicant's planning process and not less
- 5 than 30 days before applying for a CON and before substantial
- 6 expenditures to offer or develop the service are made. Under
- 7 this provision, the letter must include a brief description
- 8 of the proposed new or changed service, its location, and its
- 9 estimated cost. If requested by the sponsor, HHS was required
- 10 to make a preliminary review of the letter and inform the
- 11 sponsor of any factors likely to result in denial of a CON. The
- 12 bill also makes a conforming change to eliminate a reference to
- 13 the letter of intent procedure.
- 14 The bill amends the time frames related to the HFC's review
- 15 of CON applications. The bill requires that HHS shall complete
- 16 its formal review of the application within 30 days, rather
- 17 than the current 90 days, after acceptance of the application.
- 18 The bill also provides that failure by the council to issue a
- 19 written decision on a CON application within the time required
- 20 shall constitute approval rather than the current denial of and
- 21 final administrative action on the application.
- 22 The bill provides that any administrative rule adopted for
- 23 determining when it is not feasible to complete formal review
- 24 of an application for a CON within the time limits specified
- 25 for the HFC's final decision shall not permit a deferral of
- 26 more than 30 days, rather than the current 60 days, beyond
- 27 the time specified for a decision on the final decision,
- 28 unless both the applicant and the department agree to a longer
- 29 deferment.